APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SONKE-LAMIVUDINE+ZIDOVUDINE Film-coated tablets

Lamivudine and Zidovudine

Sugar free

Read all of this leaflet carefully before you start taking SONKE-LAMIVUDINE+ ZIDOVUDINE tablets.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SONKE-LAMIVUDINE+ ZIDOVUDINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

WARNING:

THE CLASS OF MEDICINES TO WHICH SONKE-LAMIVUDINE+ZIDOVUDINE BELONGS (NRTIS), CAN CAUSE A CONDITION CALLED LACTIC ACIDOSIS, TOGETHER WITH AN ENLARGED LIVER AND FATTY LIVER DISEASE. IT CAN BE LIFE THREATENING. LACTIC ACIDOSIS IS CAUSED BY A BUILD-UP OF LACTIC ACID IN THE BODY. DEEP, RAPID BREATHING, DROWSINESS, AND NON-SPECIFIC SYMPTOMS SUCH AS MALAISE, LOSS OF APPETITE, WEIGHT LOSS, NAUSEA, VOMITING AND

STOMACH PAIN MIGHT INDICATE THE DEVELOPMENT OF LACTIC ACIDOSIS. LACTIC ACIDOSIS CAN BE LIFE-THREATENING AND MAY CAUSE INFLAMMATION OF THE PANCREAS, LIVER FAILURE OR KIDNEY FAILURE. LACTIC ACIDOSIS, IF IT OCCURS, USUALLY DEVELOPS AFTER A FEW OR SEVERAL MONTHS OF TREATMENT.

YOUR DOCTOR WILL DISCONTINUE YOUR TREATMENT WITH SONKE-LAMIVUDINE+ZIDOVUDINE SHOULD THE ABOVE OCCUR. SONKE-LAMIVUDINE+ZIDOVUDINE WILL BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS LIVER DISEASE, OR OTHER KNOWN RISK FACTORS FOR LIVER DISEASE AND FATTY LIVER DISEASE, AS WELL AS IN OBESE (VERY OVERWEIGHT) PATIENTS, ESPECIALLY WOMEN. IF YOU ARE INFECTED WITH HIV AS WELL AS HEPATITIS C AND YOU ARE BEING TREATED WITH MEDICINES CALLED ALPHA-INTERFERON AND RIBAVIRIN, YOU MAY CONSTITUTE A SPECIAL RISK. IF YOU ARE AT INCREASED RISK YOUR HEALTH CARE PROVIDER WILL MONITOR YOUR CONDITION CLOSELY. SONKE-LAMIVUDINE+ZIDOVUDINE IS NOT USED FOR THE TREATMENT OF CHRONIC HEPATITIS B VIRUS (HBV) INFECTION AND THE SAFETY AND EFFICACY OF SONKE-LAMIVUDINE+ZIDOVUDINE HAS NOT BEEN ESTABLISHED IN PATIENTS COINFECTED WITH HBV AND HIV. IF YOU HAVE HEPATITIS B AS WELL AS HIV, YOUR HEPATITIS B MAY WORSEN IF YOU STOP TREATMENT WITHSONKE-LAMIVUDINE+ZIDOVUDINE. YOUR LIVER FUNCTION WILL BE CLOSELY MONITORED BY YOUR HEALTH CARE PROVIDER FOR AT LEAST SEVERAL MONTHS AFTER STOPPING TREATMENT WITH SONKE-LAMIVUDINE+ZIDOVUDINE. IF APPROPRIATE, YOUR DOCTOR MAY INITIATE ANTI-HEPATITIS B THERAPY.

1. What SONKE-LAMIVUDINE+ZIDOVUDINE is and what it is used for

SONKE-LAMIVUDINE+ZIDOVUDINE tablets are used as part of anti-retroviral therapy for the treatment of HIV infected adults and children over 12 years of age.

SONKE-LAMIVUDINE+ZIDOVUDINE is also used as preventive treatment (until results of blood serum tests are available) in HIV negative adults whenever there has been exposure to material known to be, or strongly suspected to be, infected with HIV. This includes

• percutaneous injury (from needles, instruments, bone fragments, etc);

• exposure of broken skin (abrasions, cuts, eczema etc);

• exposure of mucous membranes including the eye.

2. What you need to know before you take SONKE-LAMIVUDINE+ZIDOVUDINE

Do not take SONKE-LAMIVUDINE+ZIDOVUDINE

- You have previously had an allergic reaction to lamivudine, zidovudine or to any of the tablet ingredients (listed in section 6).

  (An allergic reaction may include rash, itching, swelling of the face, lips, tongue or hands/feet or breathing difficulties).
- You have blood disorders
- You are pregnant or breastfeeding
- You are younger than 12 years
- You are taking other medicine for HIV infection such as stavudine.
- You are taking a medicine called zalcitabine.
- You are taking other medicine for HIV infection containing lamivudine or medicines containing emtricitabine.

Warnings and precautions

Take special care with SONKE-LAMIVUDINE+ZIDOVUDINE

- You may still develop infections and other complications of HIV infection while using SONKE-LAMIVUDINE+ZIDOVUDINE. You should contact your doctor if you notice any signs of infection or if you are feeling unwell.
- You are still at a risk of transmission of HIV to other people through sexual contact or blood contamination, while taking SONKE-LAMIVUDINE+ZIDOVUDINE. You should continue to use appropriate precautions to prevent this.
- Stop SONKE-LAMIVUDINE+ZIDOVUDINE tablets immediately if you develop abdominal (stomach) pain, nausea or vomiting, it might indicate the development of lactic acidosis, which is serious and potentially fatal side effect.

- Blood tests may be done regularly by your doctor, as blood disorders may occur
- There is a risk factor for development of liver disease in certain susceptible patients.
- If you have a history of liver disease, including chronic active hepatitis. Patients with liver disease including chronic hepatitis B or C, who are treated with combination antiretrovirals, have a higher risk of severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to another medicine. If you have severe liver disease, do not take SONKE-LAMIVUDINE+ZIDOVUDINE.
- Patients with chronic hepatitis B or C and treated with antiretroviral therapy are at an increased risk for severe and potentially fatal hepatic adverse reactions. If you have hepatitis B or C infection, your doctor will carefully consider the best treatment regimen for you.
- The concomitant use of either ribavirin or stavudine with SONKE-LAMIVUDINE+ZIDOVUDINE should be avoided.
- SONKE-LAMIVUDINE+ZIDOVUDINE must be used with caution in patients with hepatic and renal malfunction as well as in the elderly.
- If you develop anaemia or your blood tests show a decrease in white blood cells, or you have fits or behave abnormally, you should consult your doctor.
- If you develop stomach pain, nausea or vomiting. Check with your doctor, as these could be signs of an inflamed pancreas. If you are feeling unwell, consult your doctor.
- If you notice changes in body fat (redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy), consult your doctor.
- In rare cases, as your immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection. If you are feeling unwell, consult your doctor.
- If you are co-infected with hepatitis C and receiving interferon alfa and ribavirin, you may be at special risk. It may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath).
- Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Signs of

osteonecrosis are joint stiffness, aches and pains and difficulty in movement. If you notice any of these symptoms, please inform your doctor.

Other medicines and SONKE-LAMIVUDINE+ZIDOVUDINE

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicines, even those not prescribed but obtained without a prescription.

- Care is needed if you are taking:
- Bone marrow depressants/nephrotoxic medicines (e.g. systemic pentamidine, dapsone, pyrimethamine, co-trimoxazole, amphotericin, flucytosine, ganciclovir, interferon, vincristine, vinblastine and doxorubicin)
- analgesics (pain-relieving medicines) such as paracetamol and aspirin
- cimetidine (treatment of ulcers)
- sulphonamides (bacteriostatic antimicrobial medicines)
- phenytoin (anti-epileptic medicine)
- non-steroidal anti-inflammatory medicines (reducing redness, swelling, pain)
- other nucleoside analogues including ribavirin and stavudine (treatment of HIV)
- trimethoprim/sulphamethoxazole (bacteriostatic medicines)
- other medicines containing lamivudine, to treat HIV infection or hepatitis B infection
- high doses of co-trimoxazole, an antibiotic
- emtricitabine, to treat HIV infection
- zalcitabine, to treat HIV infection
- ribavirin or injections of ganciclovir to treat viral infections
- cladribine, used to treat a certain type of leukaemia
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- rifampicin, to treat tuberculosis

- valproic acid, to treat epilepsy
- probenecid, to treat gout and similar conditions, and given with some antibiotics to make them more effective
- paracetamol, to treat pain
- interferon, to treat viral infections
- pyrimethamine, to treat malaria and other parasitic infections
- dapsone, to prevent pneumonia and treat skin infections
- fluconazole or flucytosine, to treat fungal infections such as candida
- pentamidine or atovaquone to treat parasitic infections such as Pneumocystis jirovecii pneumonia (often referred to as PCP)
- amphotericin, to treat fungal and bacterial infections
- methadone, used as a heroin substitute
- vincristine, vinblastine or doxorubicin, to treat cancer.

SONKE-LAMIVUDINE+ZIDOVUDINE with food and drink

SONKE-LAMIVUDINE+ZIDOVUDINE can be taken with or without food.

Pregnancy and breastfeeding

You must not use SONKE-LAMIVUDINE+ZIDOVUDINE when pregnant or breastfeeding your infant.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines

SONKE-LAMIVUDINE+ZIDOVUDINE may cause dizziness or tiredness in some patients. Do not drive or operate any tools or machines until you know how SONKE-LAMIVUDINE+ZIDOVUDINE affects you because your concentration may be affected.

3. How to take SONKE-LAMIVUDINE+ZIDOVUDINE

Do not share medicines prescribed for you with any other person.

Adults and children over 12 years of age:

The usual dose is 1 SONKE-LAMIVUDINE+ZIDOVUDINE tablet twice daily, with or without food.

Post Exposure prevention treatment:

You should start taking SONKE-LAMIVUDINE+ZIDOVUDINE as soon as possible (1-2 hours) after the exposure has occurred.

The usual dose is one SONKE-LAMIVUDINE+ZIDOVUDINE tablet twice a day to be taken for 28 days if the source material is confirmed to be infected with HIV. Treatment will be stopped immediately by your doctor if the source material is not infected with HIV.

To help you remember to take SONKE-LAMIVUDINE+ZIDOVUDINE, try to get into the habit of taking it at the same time each day.

Take SONKE-LAMIVUDINE+ZIDOVUDINE as directed and for as long as directed; do not stop them, even if you feel better, as the symptoms may return.

If you have the impression that the effect of SONKE-LAMIVUDINE+ZIDOVUDINE tablets is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more SONKE-LAMIVUDINE+ZIDOVUDINE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take SONKE-LAMIVUDINE+ZIDOVUDINE

Take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SONKE-LAMIVUDINE+ZIDOVUDINE can have side effects.

Not all side effects reported for SONKE-LAMIVUDINE+ZIDOVUDINE are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking SONKE-LAMIVUDINE+ZIDOVUDINE, please consult your health care provider for advice.

If any of the following happens, stop taking SONKE-LAMIVUDINE+ZIDOVUDINE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, hives, itching, wheezing, shortness of breath or swelling of the face, lips, tongue, hands/ feet, fainting, high temperature

These are all very serious side effects. If you have them, you may have had a serious reaction to SONKE-LAMIVUDINE+ZIDOVUDINE**.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital of you notice any of the following:

- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis); symptoms include:
    - dark, reddish urine, a decreased amount of urine, weakness and muscle aches.
- signs of recurrent infections such as fever and sore throat
- fits (convulsions)
- chest pain; disease of the heart muscle
- difficulty breathing
- Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs. Lactic acidosis is more likely to develop in people who have liver disease, or in obese (very overweight) people, especially women.
- Signs of lactic acidosis include:
    - deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, feeling sick (nausea), being sick (vomiting), stomach pain.
- Inflammation of the liver (hepatitis); symptoms include:

- yellow skin or eyes (jaundice), nausea, fatigue and fever.

- Inflammation of the pancreas (pancreatitis); symptoms include severe stomach pain with nausea and vomiting and fever.

These are all very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently reported side effects:

• difficulty in sleeping

• cough

• irritated, runny nose

• diarrhoea

• hair loss

• an area of swelling of the lower layer of skin and tissue just under the skin or mucous membranes

• muscle pain and discomfort

• joint pain

• tiredness, lack of energy

• a low red blood cell count (anaemia) or low white blood cell count (neutropenia or leukopenia)

• an increase in the level of liver enzymes

• an increased amount in the blood of bilirubin (a substance produced in the liver) which may make

• general feeling of being unwell

• inflammation caused by over-active immune system.

• difficulty in sleeping

Less frequently reported side effects

• a decrease in the number of cells involved in blood clotting (thrombocytopenia)

• a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)

• tingly feelings in the skin (pins and needles)

• weakness, numbness, pain

- an increase in an enzyme called amylase
- breakdown of muscle tissue
- a decrease in the number of all kinds of blood cells (pancytopenia)
- a failure of the bone marrow to produce new red or white blood cells (aplastic anaemia)
- feeling depressed or anxious, not being able to concentrate, feeling drowsy
- feeling bloated
- indigestion, taste disturbance
- changes in the colour of nails, your skin or the skin inside your mouth
- passing urine more often
- enlarged breasts in men.
- a flu-like feeling – chills and sweating
- physical weakness
- neurological effects that starts later.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SONKE-LAMIVUDINE+ZIDOVUDINE

5. How to store SONKE-LAMIVUDINE+ZIDOVUDINE

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- Keep the blister in the outer carton.
- Protected from light/moisture.
- Do not use after the expiry date stated on the label.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems

6. Contents of the pack and other information

What SONKE-LAMIVUDINE+ZIDOVUDINE contains

Each SONKE-LAMIVUDINE+ZIDOVUDINE tablet contains 150 mg lamivudine and 300 mg zidovudine (active substances).

The other ingredients are:

Tablet core: Colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycollate

Film coat: Opadry white 03H58900 consisting of hypromellose; titanium dioxide & propylene glycol.

What SONKE-LAMIVUDINE+ZIDOVUDINE looks like and contents of the pack

White to off-white, film-coated capsule shaped tablets debossed with 'RX923' on one side and plain on the other side.

10 Tablets are packed in blister strips of clear, transparent, PVC film with an aluminium foil backing.

Cartons contain 10, 30, 60 or 100 tablets.

60 Tablets packed in White opaque HDPE Bottle.

Holder of Certificate of Registration

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